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UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

DORINDA VASSIGH and SAMANTHA LEWIN, individually and on behalf of all others similarly situated,

**Case No.**

**Plaintiffs,**

V.

BAI BRANDS LLC.,

## CLASS ACTION COMPLAINT

## **JURY TRIAL DEMANDED**

**Defendant.**

1 Plaintiffs Dorinda Vassigh and Samantha Lewin (“Plaintiffs”) bring this action on behalf of  
 2 themselves and all others similarly situated against Defendant Bai Brands LLC (“Bai Brands” or  
 3 “Defendant”). Plaintiffs make the following allegations pursuant to the investigation of their  
 4 counsel and based upon information and belief, except as to the allegations specifically pertaining  
 5 to themselves, which are based on personal knowledge.

6 **INTRODUCTION**

7 1. Bai Brands’ marketing campaign takes advantage of intense consumer demand for  
 8 antioxidants in precisely the manner the Food and Drug Administration (“FDA”) and  
 9 corresponding California law has deemed misleading and unlawful. Bai Brands has plastered  
 10 misleading antioxidant messaging on every square inch of labeling of its Bai5 Antioxidant  
 11 Infusions beverage, including the bottle’s cap. The simple truth is, however, that Bai5 Antioxidant  
 12 Infusions does not have even a single nutrient recognized or approved for nutrient content claims  
 13 using the term “antioxidant.” Accordingly, Bai Brands has sold misbranded products using  
 14 misleading advertising to thousands, if not millions, of California consumers, who relied on  
 15 Defendant’s advertising and were injured as a result.

16 2. Plaintiffs Vassigh and Lewin purchased numerous bottles of Bai5 Antioxidant  
 17 Infusions based on Defendant’s misleading advertising on the labels of the product. Plaintiffs  
 18 assert claims on behalf of themselves and a California class of purchasers of Bai5 Antioxidant  
 19 Infusions<sup>1</sup> for violation of the California Consumer Legal Remedies Act (“CLRA”), for violation  
 20 of the California Unfair Competition Law (“UCL”), and for violation of the California False  
 21 Advertising Law (“FAL”).

22 **PARTIES**

23 3. Plaintiff Dorinda Vassigh is a citizen of California, residing in San Francisco. From  
 24 the spring of 2013 until the summer of 2014, Ms. Vassigh purchased Bai5 Antioxidant Infusions,  
 25 including Bai5 Antioxidant Infusions: Molokai Coconut, about once a month. Ms. Vassigh

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26 <sup>1</sup> Bai5 Antioxidant Infusions comes in the following flavors: Brasilia Blueberry, Jamaica Blue  
 27 Berry, Malawi Mango, Molokai Coconut, Ipanema Pomegranate, Sumutra Dragonfruit, Costa Rica  
 28 Clementine, Tanzania Lemonade Tea, Congo Pear, Panama Peach, Limu Lemon. The term “Bai5  
 Antioxidant Infusions” encompasses all of these flavors.

1 purchased bottles of Bai5 Antioxidant Infusions from multiple retail stores, including Whole Foods  
2 and 26<sup>th</sup> & Guerrero Market in San Francisco, California. Ms. Vassigh purchased bottles of Bai5  
3 Antioxidant Infusions relying on statements and graphics made on the bottles' labels, including  
4 statements and graphics characterizing antioxidants such as "Antioxidant Infusions," "Antioxidant  
5 Packed Beverage," "Antioxidant Packed," "We infuse the antioxidant power of the superfruit, add  
6 a splash of exotic fruit juices and voila! You have 100% natural, free-radical crushing, Bai 5,"  
7 "Antioxidant Goodness Inside," "Hello Antioxidants!," and the "thermometer" graphic discussed  
8 below. Ms. Vassigh would not have purchased Bai5 Antioxidant Infusions, or would have paid  
9 significantly less for the products, had she known that these statements were unauthorized, and that  
10 Defendant misbranded the products and mischaracterized the amounts and nature of the nutrients  
11 and antioxidants inside. Ms. Vassigh suffered injury in fact and lost money as a result of Bai  
12 Brands' deceptive, misleading, unfair and fraudulent practices described herein.

13       4. Plaintiff Samantha Lewin is a citizen of California, residing in San Francisco.  
14 Within the past two years, Ms. Lewin purchased Bai5 Antioxidant Infusions, including Bai5  
15 Antioxidant Infusions: Molokai Coconut and Bai5 Antioxidant Infusions: Ipanema Pomegranate  
16 from multiple retail stores in California, including Walgreens, and online at Amazon.com. Ms.  
17 Lewin purchased bottles of Bai5 Antioxidant Infusions relying on statements and graphics made on  
18 the bottles' labels, including statements and graphics characterizing antioxidants such as  
19 "Antioxidant Infusions," "Antioxidant Packed Beverage," "Antioxidant Packed," "We infuse the  
20 antioxidant power of the superfruit, add a splash of exotic fruit juices and voila! You have 100%  
21 natural, free-radical crushing, Bai 5," "Antioxidant Goodness Inside," "Hello Antioxidants!," and  
22 the "thermometer" graphic discussed below. Ms. Lewin would not have purchased Bai5  
23 Antioxidant Infusions, or would have paid significantly less for the products, had she known that  
24 these statements were unauthorized, and that Defendant misbranded the products and  
25 mischaracterized the amounts and nature of the nutrients and antioxidants inside. Ms. Lewin  
26 suffered injury in fact and lost money as a result of Bai Brands' deceptive, misleading, unfair and  
27 fraudulent practices described herein.

5. Defendant Bai Brands LLC is a New Jersey corporation located at 1800 E. State Street, Suite 153, Hamilton, New Jersey 08609. Bai Brands manufactures, advertises, sells, distributes, and markets Bai5 Antioxidant Infusions as alleged herein nationwide, including in California.

## **JURISDICTION AND VENUE**

6. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332(d)(2)(A) because this case is a class action where the aggregate claims of all members of the proposed class are in excess of \$5,000,000, exclusive of interests and costs, and Plaintiffs, as well as most members of the proposed class, are citizens of states different from the states of Defendant. Defendant has sold hundreds of thousands, if not millions, of bottles of Bai5 Antioxidant Infusions.

7. Pursuant to 28 U.S.C. § 1391, this Court is the proper venue for this action because a substantial part of the events, omissions and acts giving rise to the claims herein occurred in this District. Defendant distributed, advertised, and sold Bai5 Antioxidant Infusions, which is the subject of the present complaint, in California and in this District. Moreover, Plaintiffs read the product's label and purchased Bai5 Antioxidant Infusions in this District.

## **FACTS COMMON TO ALL CAUSES OF ACTION**

## Bai Brands' Unlawful Characterization of Antioxidants

8. Bai Brands' marketing campaign for Bai5 Antioxidant Infusions advertises one basic promise: consumers should buy Bai5 Antioxidant Infusions because it is packed with beneficial antioxidants, full stop. Defendant's advertising flies in the face of identical California and federal laws that bar manufacturers from spouting "antioxidant" advertising without backing up their claims and misleading consumers into believing that all antioxidants are created equal.

9. Specifically, by law, Defendant must disclose on the labels of Bai5 Antioxidant Infusions precisely which *nutrients* have antioxidant properties. Further, each of these nutrients must have established Reference Daily Intake (“RDI”) standards set by the FDA to prevent manufacturers from claiming that any obscure fruit or vegetable, or in this case, Defendant’s “Superfruit.” is a nutritional source of antioxidants.

1       10. Here, Bai5 Antioxidant Infusions claims to be an “Antioxidant Packed” beverage,  
 2 but does not contain even a single nutrient with an established RDI. As such, Defendant’s labels  
 3 are misbranded and misleading.

4       11. Almost every written word and graphic on the labels of Bai5 Antioxidant Infusions,  
 5 including the bottles’ caps, makes promises about and characterizes the antioxidants inside.  
 6 Although Bai5 Antioxidant Infusions comes in several flavors, including Brasilia Blueberry,  
 7 Jamaica Blue Berry, Malawi Mango, Molokai Coconut, Ipanema Pomegranate, Sumutra  
 8 Dragonfruit, Costa Rica Clementine, Tanzania Lemonade Tea, Congo Pear, Panama Peach, Limu  
 9 Lemon, each and every one of these various flavors bears identical graphics and substantially  
 10 identical statements concerning antioxidants. Each of the flavors of Bai5 Antioxidant Infusions  
 11 contain the same misleading and unlawful common message concerning antioxidants. As seen in  
 12 the picture below, the only difference between the flavors is a different fruit pictured on the front  
 13 label, and a different respective fruit flavor listed in the ingredients.<sup>2</sup>



15       12. The name ‘**Bai5 Antioxidant Infusions**’ appears in bold, large letters on the front  
 16 of the label. On the bottom, the label states “Superfruit Infused, Antioxidant Packed.”

27       2 For the purposes of this Complaint, any statements made or graphics show of any of the various  
 28 flavors Bai5 Antioxidant Infusions that concern antioxidants apply to all flavors of Bai5  
 Antioxidant Infusions.



13. The twist-off cap of Bai5 Antioxidant Infusions' bottles bears the following  
statement, "Superfruit Infused. Antioxidant Packed."

14. The side of Bai5 Antioxidant Infusions' labels state "**Meet Our Superfruit**" in  
large bold letters, and show a picture of "**The Superfruit**" directly below. The "Superfruit" is in  
fact the outside skin of coffee fruit. Underneath the picture, the label states:

You've probably met the inside of coffeefruit, what your everyday cup'o joe is made from.  
But we'd like to introduce you to the outside; coffee's secret superfruit.

1 Can something made with coffeefruit taste fruity and refreshing? Of Course, just because it  
 2 says "coffee" doesn't mean it tastes like it.

3 We infuse the antioxidant power of the superfruit, add a splash of exotic fruit juices and  
 4 voila! You have 100% natural, free-radical crushing, Bai 5.

5 A picture of the side label is reproduced below:



15. The back of Bai5 Antioxidant Infusions' labels bear a transparent "thermometer"  
 16 graphic, suggesting to consumers that the more of the beverage they drink, the more effective and  
 17 abundant their antioxidant intake will be. Consumers are prompted to see the amount of beverage  
 18 left in the bottle through the transparent thermometer, and to associate those levels with the  
 19 effectiveness and nature of the antioxidants they just consumed. On the side of the thermometer  
 20 graphic, the label states "Antioxidant Goodness Inside." The "degrees" of the thermometer are  
 21 marked by statements concerning antioxidants, suggesting that the more beverage consumed, the  
 22 more effective the antioxidant concoction will be. The "degrees" read, from top to bottom, "Feel  
 23  
 24  
 25  
 26  
 27  
 28

1 the Infusion," "Hello Antioxidants!," "Bring It On," "Good Bai Free Radicals," and "Superfruit  
 2 Master." In other words, after a few sips of the beverage, customers can "Feel the Infusion" of  
 3 antioxidants, and by the end of the bottle, they become "Superfruit Masters." The referred to  
 4 graphic is depicted below:



1                   **Bai Brands Is Misbranded Under Identical California And Federal Laws**

2                   16. Identical federal and California laws regulate the content of labels on packaged  
 3 food. The requirements of the federal Food, Drug & Cosmetic Act (“FDCA”) were adopted by the  
 4 California legislature in the Sherman Food Drug & Cosmetic Law (the “Sherman Law”). Under  
 5 California law “[a]ny food is misbranded if its labeling does not conform with the requirements for  
 6 nutrient content or health claims as set forth in Section 403(r) [21 U.S.C. Sec. 343(r)] of the federal  
 7 act and the regulations adopted pursuant thereto.” California Health & Safety Code § 110670.

8                   17. Nutrient content claims using the term “antioxidant” must also comply with the  
 9 requirements listed in 21 C.F.R. 101.54(g). Under 21 C.F.R. § 101.54(g), a nutrient content claim  
 10 that characterizes the level of antioxidant nutrients present in a food may only be used if: “(1) An  
 11 RDI (Reference Daily Intake) has been established for each of the nutrients; (2) The nutrients that  
 12 are the subject of the claim have recognized antioxidant activity … ; (3) The level of each nutrient  
 13 that is the subject of the claim is sufficient to qualify for the [type of claim made]; and (4) The  
 14 names of the nutrients that are the subject of the claim are included as part of the claim (e.g., ‘high  
 15 in antioxidant vitamins C and E’). Alternatively, when used as part of a nutrient content claim, the  
 16 term ‘antioxidant’ or ‘antioxidants’ (as in ‘high in antioxidants’) may be linked by a symbol (e.g.  
 17 an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product  
 18 label followed by the name or names of the nutrients with recognized antioxidant activity.” The  
 19 use of a nutrient content claim that uses the term “antioxidant” but does not comply with the  
 20 requirements of 21 C.F.R. 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

21                   18. The regulations regarding antioxidant nutrient content claims have been made clear  
 22 by prior FDA actions targeting similar or identical claims. For example, on August 23, 2010, the  
 23 FDA sent Unilever, Inc. a warning letter that specifically identified unauthorized antioxidant  
 24 nutrient content claims that Unilever made on Lipton Green Tea’s label and on its website. In the  
 25 letter, the FDA explained that the statement “LIPTON Tea is made from tea leaves rich in naturally  
 26 protective antioxidants,” did not comply with 21 C.F.R. 101.54(g) because it did not “include the  
 27 nutrients that are the subject of the claim or use a symbol to link the term ‘antioxidant’ to those

1 nutrients.” Accordingly, the FDA determined that the claim misbranded Lipton Green Tea under  
 2 section 403(r)(2)(A)(i) of the Act. Likewise, the FDA concluded that the statement “packed with  
 3 protective FLAVONOID ANTIOXIDANTS” did not comply with 21 C.F.R. 101.54(g) because no  
 4 RDI has been established for flavonoids. Because the statements were unauthorized nutrient  
 5 content claims, the FDA concluded that Lipton Green Tea was misbranded.<sup>3</sup>

6       19. In another example, on February 22, 2010, the FDA sent a letter to Redco Foods,  
 7 Inc. warning Redco that its green tea products violated the FDCA. The FDA determined that  
 8 Redco’s green tea label bore the following unauthorized nutrient content claim:

9               One of the antioxidants known as EGCG (Epigallocatechin gallate) is abundantly found in  
 10 tea leaves.

11          The FDA determined that the claim did not comply with 21 C.F.R. 101.54(g)(1) because no  
 12 RDI has been established for EGCG.<sup>4</sup>

13       20. The FDA has explained that 21 C.F.R. 101.54(g) can be violated even where a  
 14 nutrient with an established RDI is present in a food bearing a label using the term “antioxidant” if  
 15 the nutrient with the established RDI does not account for 100% of the claimed antioxidant value.  
 16 On August 30, 2010, the FDA sent a letter to the Dr Pepper Snapple Group, manufacturers of  
 17 Canada Dry Sparkling Green Tea Ginger Ale, warning that its labels were misbranded pursuant to  
 18 21 C.F.R. 101.54(g). The FDA explained:

19               The nutrient content claim for your Sparkling Green Tea Ginger Ale product of  
 20 “ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN  
 21 C\*\* .... \*\*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids  
 22 and Vitamin C” identifies Vitamin C as a nutrient associated with the antioxidant claim.  
 23 Vitamin C is a nutrient that is a recognized source of antioxidants. Your Nutrition Facts  
 24 panel declares Vitamin C at 100% of the Daily Reference Value (DRV), which accounts for  
 25 60 mg of the claimed 200 mg of antioxidants. According to the nutrient content claim on  
 26 your product label, the remainder 140 mg of antioxidants must be derived from green tea or  
 27 green tea flavonoids, which are not nutrients with recognized antioxidant activity under 21  
 28 CFR § 101.54(g)(2). Therefore, the claim ‘ENHANCED WITH 200 mg OF  
 ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\* .... \*\*Each 8 oz serving  
 contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C” does not meet

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<sup>3</sup> See 8/23/2010 FDA Warning Letter to Unilever, Inc. attached hereto as Exhibit A.

<sup>4</sup> See 2/22/2010 FDA Warning Letter to Redco Foods, Inc. attached hereto as Exhibit B.

1           the requirements of 21 CFR 101.54(g) and misbrands your product under section  
 2           403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)].<sup>5</sup>

3           21. Of particular relevance here, the labels of Bai5 Antioxidant Infusions claim that the  
 4           products' "Antioxidant Blend" consists of "Organic Coffeefruit & White Tea Extract." On April  
 5           20, 2011, the FDA sent a letter to Diaspora Tea & Herb Co., LLC, the manufacturer of Rishi brand  
 6           teas, warning the company that its White Tea products were misbranded. The FDA determined  
 7           that the following label claim was an unauthorized nutrient content claim pursuant to 21 C.F.R.  
 8           101.54(g)(1) because "White Tea" does not have an established RDI: "White Tea...contain[s] high  
 9           concentrations of ...antioxidant polyphenols (tea catechins)..."<sup>6</sup> (Omissions and alterations in  
 10           original).

11           22. The FDA further clarified the requirements of 21 C.F.R. 101.54(g) in compliance  
 12           guides concerning the use of the term "antioxidant" on food labels. In a June 2008 "Guidance for  
 13           Industry" document, the FDA made the requirements of 21 C.F.R. 101.54(g) pristinely clear:

14           Does the label claim have to include the name of the nutrient that is an antioxidant, or can  
 15           the claim simply say "antioxidants?"

16           The names of the nutrients that are the antioxidants must appear in the claim. For example,  
 17           "high in antioxidant vitamins C and E."<sup>7</sup>

18           23. Here, Bai Brands' entire marketing campaign for Bai5 Antioxidant Infusions is  
 19           centered on the characterization of antioxidants in the products and the use of nutrient content  
 20           claims using the term "antioxidant."

21           24. The name of Bai5 Antioxidant Infusions instructs consumers that they are  
 22           purchasing a beverage "infused" with antioxidants. Bai Brands markets the antioxidant  
 23           characteristics of Bai5 Antioxidant Infusions as the primary reasons for purchasing the products.

24  
 25           <sup>5</sup> See 8/30/2010 FDA Warning Letter to Dr Pepper Snapple Group, attached hereto as Exhibit C.

26           <sup>6</sup> See 4/20/2011 FDA Warning Letter to Diaspora Tea & Herb Co., LLC attached hereto as Exhibit  
 27           D.

28           <sup>7</sup> *Guidance for Industry: Food Labeling; Nutrient Content Claims; Definition for "High Potency"*  
          *and Definition for Antioxidant" for Use in Nutrient Content Claims for Dietary Supplements and*  
          *Conventional Foods*, at 5 (June 2008). Available at  
<http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-1995-N-0400-GDL.pdf>

1 In turn, consumers rely on Bai Brands' characterization of antioxidants in Bai5 Antioxidant  
 2 Infusions when purchasing the products.

3 25. Bai Brands' antioxidant advertising does not stop with the product's name, but is  
 4 rather the entire platform behind its multimillion dollar marketing campaign. Bai Brands  
 5 characterizes antioxidants on the labels of Bai5 Antioxidant Infusions through statements such as:

- 6 • "Superfruit Infused, Antioxidant Packed Beverage"
- 7 • "Antioxidant Packed"
- 8 • "Antioxidant Goodness Inside"
- 9 • "Hello Antioxidants!"
- 10 • "We infuse the antioxidant power of the superfruit, add a splash of exotic fruit  
 11 juices and voila! You have 100% natural, free-radical crushing, Bai 5."

12 26. Bai5 Antioxidant Infusions' labels further characterize antioxidants by containing a  
 13 "thermometer" chart spanning the entire length of the labels depicting the amount and nature of  
 14 antioxidants inside. The thermometer "gauge" is transparent, so that customers can see the  
 15 amounts of the beverage left in the bottle as they are drinking and associate these levels with the  
 16 levels and effectiveness of antioxidants in the product. From top to bottom, the thermometer chart  
 17 contains statements, analogous to the "degrees" on a thermometer, which depict the amounts and  
 18 nature of the antioxidants the customer has just consumed. These statements read, from top to  
 19 bottom, "Feel The Infusion," "Hello Antioxidants!," ""Bring It On," "Good Bai Free Radicals,"  
 20 and "Superfruit Master."

21 27. However, the labels of Bai5 Antioxidant Infusions do not even state which nutrients,  
 22 if any, are the subject of their antioxidant claims. There is no symbol that refers to another symbol  
 23 somewhere else on the label followed by the name or names of the nutrients with recognized  
 24 antioxidant activity.

25 28. Bai5 Antioxidant Infusions does not contain a single nutrient with an established  
 26 RDI. Bai5 Antioxidant Infusions' label specifically states that the product is "Not a significant  
 27 source of...vitamin A, vitamin C, calcium, and iron." Just below the "Nutritional Facts" portion of  
 28

1 Bai5 Antioxidant Infusions' labels, the label states "Bai 5 Proprietary Antioxidant Blend: Organic  
 2 Coffeefruit & White Tea Extract." Organic Coffeefruit and White Tea Extract are not "nutrients"  
 3 within the scope 21 C.F.R. 101.54(g), and, even if they were, they do not have established RDI's as  
 4 required by law. In fact, the FDA has determined that tea is a "food[] of no nutritional  
 5 significance."<sup>8</sup>

#### **Consumers Are Misled By Bai Brands' Unlawful Antioxidant Marketing**

7 29. Bai Brands' antioxidant advertising is a calculated ruse to capitalize on consumers'  
 8 craving for products with antioxidants.<sup>9</sup> However, identical federal and California law bans such  
 9 advertising because it is misleading.

10 30. The FDA specifically proposed paragraph (g) to 21 C.F.R. 101.54 to "ensure that  
 11 consumers are not confused or misled" by nutrient content claims using the term "antioxidants."<sup>10</sup>  
 12 The FDA's proposal to add a regulation to standardize nutrient content claims using the term  
 13 "antioxidants" followed an informal FDA survey that found that claims like "high in antioxidants"  
 14 often referred "to a variety of nutrients and other dietary ingredients that are present in widely  
 15 varying amounts." The FDA concluded that such inconsistent use of antioxidant nutrient content  
 16 claims "lead to consumer confusion."

17 31. The FDA noted that part of the confusion stems from the fact that:

18 The term 'antioxidants' is unique in comparison to the names of other nutrients associated  
 19 with nutrient content claims. Unlike previously approved nutrient content claims that  
 20 characterize the level of a particular nutrient (e.g., 'low sodium'), a term such as 'high in  
 21 antioxidants' ties a claim (i.e., 'high') to a class of nutrients that share a specific  
 22 characteristic (i.e., they are antioxidants) whose very name indicates a metabolic function.

23 32. Accordingly, because the use of the term "antioxidant" implies health benefits, the  
 24 FDA specifically sought to curtail the use of antioxidant statements related to food products that *do*

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25 <sup>8</sup> FDA Food Labeling Guide, at p. 64 available at  
<http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf>

26 <sup>9</sup> According to a consumer survey by Bossa Nova, half of adults rank antioxidants as the top  
 27 nutrient they are most concerned about adding to their diets – ahead of calcium, fiber and iron. See  
New Survey Finds Antioxidants #1 Nutrient Concern Amongst Consumers, PR Newswire.  
[http://www.prnewswire.com/news-releases/new-survey-finds-antioxidants-1-nutrient-concern-](http://www.prnewswire.com/news-releases/new-survey-finds-antioxidants-1-nutrient-concern-amongst-consumers-106440093.html)  
 amongst-consumers-106440093.html.

28 <sup>10</sup> *Food Labeling; Nutrient Content Claims: Definition of "Antioxidant" for Use in Nutrient  
 Content Claims*, 21 C.F.R. Part 101, Federal Register Vol. 60 No. 249, pp. 67184-67194, at 67189  
 (Dec. 28, 1995). Available at <http://www.gpo.gov/fdsys/pkg/FR-1995-12-28/pdf/95-31194.pdf>

1       not contain nutrients recommended for the daily diet. In the FDA's view, consumers are misled  
 2 and confused when products are advertised as "packed" with antioxidants, "high in" antioxidants,  
 3 a source of "many" antioxidants, or "infused" with antioxidants, but, like Bai5 Antioxidant  
 4 Infusions, do not contain even a single nutrient with an established RDI.

5           33. Medical professionals agree. For example, Jeffrey B. Blumberg, PhD, a professor  
 6 and the director of the Antioxidants Research Laboratory at Tufts University explained that the one  
 7 "problem" with the "Antioxidant Message" that products are "high or rich in antioxidants" is that it  
 8 deceives consumers by "making people think it's no longer the vitamins, minerals, or fiber but only  
 9 the phytochemicals that promote health ... But the reason plant foods are good for you is because  
 10 of *everything* they contain. There's synergy for all of these ingredients – synergies between  
 11 ingredients in one food and between multiple foods."<sup>11</sup>

12           34. The Harvard School of Public Health has also opined that it is critical to  
 13 differentiate between different types of antioxidants, as the FDA has done through its requirement  
 14 that manufacturers list nutrients with established RDI's any time they make nutrient content claims  
 15 using the term "antioxidant." The Harvard School of Public Health Nutrition Source, an online  
 16 publication of the School of Public Health, instructs that "using the term 'antioxidant' to refer to  
 17 substances is misleading. It is really a chemical property, namely, the ability to act as an electron  
 18 donor. Some substances that act as antioxidants in one situation may be prooxidants—electron  
 19 grabbers—in a different chemical milieu. Another big misconception is that antioxidants are  
 20 interchangeable. They aren't. Each one has unique chemical behaviors and biological properties.  
 21 They almost certainly evolved as parts of elaborate networks, with each different substance (or  
 22 family of substances) playing slightly different roles. This means that no single substance can do  
 23 the work of the whole crowd."<sup>12</sup>

25           <sup>11</sup> *That's why the Dietary Guidelines for Americans recommends we consume a diversity of fruits,  
 26 vegetables, and whole grains."*" Palmer, Sharon, *Dietary Antioxidants – Do Foods and  
 27 Supplements With High Antioxidant Values Guarantee Better Health?* Vol. 15 No. 4 P. 42 (Apr.  
 28 2013) (emphasis added) available at  
<http://www.todaysdietitian.com/newarchives/040113p42.shtml>.

<sup>12</sup> *Antioxidants: Beyond the Hype*, Harvard School of Public Health Source, available at  
<http://www.hsph.harvard.edu/nutritionsource/antioxidants/>

1       35. The FDA's and Dr. Blumberg's conclusions about consumer confusion are well  
 2 founded, as a "recent study conducted by researchers at the University of Houston found that  
 3 simply placing a healthy euphemism [like antioxidant] on a food package made people believe it  
 4 was healthier than others that made no obvious health claims."<sup>13</sup> Here, Bai5 Antioxidant Infusions  
 5 mislead consumers into believing that the products are superior because they have been "infused"  
 6 and "packed" with antioxidants, even though the products do not contain a single nutrient with an  
 7 established RDI.

8       36. Defendant has made, and continues to make, unlawful and misleading claims on the  
 9 food labels of Bai5 Antioxidant Infusions that are prohibited by identical federal and California  
 10 laws and which render these products misbranded. Under federal and California law, Bai5  
 11 Antioxidant Infusions cannot legally be manufactured, advertised, distributed, held, or sold.  
 12

#### **CLASS REPRESENTATION ALLEGATIONS**

13       37. Plaintiffs seek to represent a class defined as all persons in California who  
 14 purchased Bai5 Antioxidant Infusions, excluding those that made such purchase for purpose of  
 15 resale (the "Class").  
 16

17       38. Defendant sells hundreds of thousands of bottles of Bai5 Antioxidant Infusions.  
 18 Bai5 Antioxidant Infusions is available in major supermarkets across California. Accordingly,  
 19 members of the Class are so numerous that their individual joinder herein is impracticable. The  
 20 precise number of Class members and their identities are unknown to Plaintiffs at this time but may  
 21 be determined through discovery. Class members may be notified of the pendency of this action  
 22 by mail and/or publication through the distribution records of Defendant, third party retailers, and  
 23 vendors.  
 24

25       39. Common questions of law and fact exist as to all Class members and predominate  
 26 over questions affecting only individual Class members. Common legal and factual questions  
 27 include, but are not limited to whether Bai5 Antioxidant Infusions is misbranded, and whether the  
 28 labeling, marketing and promotion of Bai5 Antioxidant Infusions is false and misleading.  
 29

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<sup>13</sup> See *Healthy Labels Magic Words Regardless of Food Inside* (June 19, 2014) available at <http://guardianlv.com/2014/06/healthy-labels-magic-words-regardless-of-the-food-inside/>

1       40. The claims of the named Plaintiffs are typical of the claims of the Class in that the  
 2 named Plaintiffs were exposed to Defendant's false, misleading and misbranded labels, purchased  
 3 Bai5 Antioxidant Infusions, and suffered losses as a result of those purchases.  
 4

5       41. Plaintiffs are adequate representatives of the Class because their interests do not  
 6 conflict with the interests of the Class members they seek to represent, they have retained  
 7 competent counsel experienced in prosecuting class actions, and they intend to prosecute this  
 8 action vigorously. The interests of Class members will be fairly and adequately protected by  
 9 Plaintiffs and their counsel.

10      42. The class mechanism is superior to other available means for the fair and efficient  
 11 adjudication of the claims of the Class members. Each individual Class member may lack the  
 12 resources to undergo the burden and expense of individual prosecution of the complex and  
 13 extensive litigation necessary to establish Defendant's liability. Individualized litigation increases  
 14 the delay and expense to all parties and multiplies the burden on the judicial system presented by  
 15 the complex legal and factual issues of this case. Individualized litigation also presents a potential  
 16 for inconsistent or contradictory judgments. In contrast, the class action device presents far fewer  
 17 management difficulties and provides the benefits of single adjudication, economy of scale, and  
 18 comprehensive supervision by a single court on the issue of Defendant's liability. Class treatment  
 19 of the liability issues will ensure that all claims and claimants are before this Court for consistent  
 20 adjudication of the liability issues.

**COUNT I**

**Violation Of California's Consumers Legal Remedies Act,  
 California Civil Code §§ 1750, *et seq.***

21      43. Plaintiffs hereby incorporate by reference the allegations contained in all preceding  
 22 paragraphs of this complaint.

23      44. Plaintiffs bring this claim individually and on behalf of the members of the  
 24 proposed Class against Defendant.  
 25  
 26  
 27  
 28

1       45. Plaintiffs and Class members are consumers who purchased Bai5 Antioxidant  
 2 Infusions for personal, family or household purposes. Plaintiffs and the Class members are  
 3 “consumers” as that term is defined by the CLRA in Cal. Civ. Code § 1761(d). Plaintiffs and the  
 4 Class members are not sophisticated experts with independent knowledge of the character,  
 5 effectiveness, nature, level, or amount of antioxidants found Bai5 Antioxidant Infusions or  
 6 coffeefruit or white tea extracts.

7       46. Bai5 Antioxidant Infusions beverages that Plaintiffs and other Class members  
 8 purchased from Defendant were “goods” within the meaning of Cal. Civ. Code § 1761(a).

9       47. Defendant’s actions, representations, and conduct have violated, and continue to  
 10 violate the CLRA, because they extend to transactions that intended to result, or which have  
 11 resulted in, the sale of goods to consumers.

12       48. Defendant’s antioxidant nutrient content claims including, “Antioxidant Infusions,”  
 13 “Antioxidant Packed Beverage,” “Antioxidant Packed,” “We infuse the antioxidant power of the  
 14 superfruit, add a splash of exotic fruit juices and voila! You have 100% natural, free-radical  
 15 crushing, Bai 5,” “Antioxidant Goodness Inside,” “Hello Antioxidants!” and the “thermometer”  
 16 graphic discussed above characterize the level of antioxidants in Bai5 Antioxidant Infusions and  
 17 violate federal and California law because (1) there are no nutrients with RDIs in Bai5 Antioxidant  
 18 Infusions, and (2) the antioxidant nutrient content claims do not include the nutrients that are  
 19 subject of the claims or use a symbol to link the term “antioxidant” to those nutrients. Because  
 20 Defendant’s nutrient content claims do not comply with 21 C.F.R. § 101.54(g), Defendant sold  
 21 misbranded products in California during the Class Period.

22       49. California’s Consumers Legal Remedies Act, Cal. Civ. Code § 1770(a)(5), prohibits  
 23 “[r]epresenting that goods or services have sponsorship, approval, characteristics, ingredients, uses,  
 24 benefits, or quantities which they do not have or that a person has a sponsorship, approval, status,  
 25 affiliation, or connection which he or she does not have.” By engaging in the conduct set forth  
 26 herein, Defendant violated and continues to violate Section 1770(a)(5) of the CLRA, because

1 Defendant's conduct constitutes unfair methods of competition and unfair or fraudulent acts or  
2 practices, in that it misrepresents the particular characteristics, benefits and quantities of the goods.  
3

4 50. Cal. Civ. Code § 1770(a)(7) prohibits representing that goods or services are of a  
particular standard, quality, or grade, or that goods are of a particular style or model, if they are of  
5 another. By engaging in the conduct set forth herein, Defendant violated and continues to violate  
6 Section 1770(a)(7) of the CLRA, because Defendant's conduct constitutes unfair methods of  
7 competition and unfair or fraudulent acts or practices, in that it misrepresents the particular  
8 standard, quality or grade of the goods.  
9

10 51. Cal. Civ. Code § 1770(a)(9) further prohibits “[a]dvertising goods or services with  
intent not to sell them as advertised.” By engaging in the conduct set forth herein, Defendant  
11 violated and continues to violate Section 1770(a)(9), because Defendant's conduct constitutes  
12 unfair methods of competition and unfair or fraudulent acts or practices, in that it advertises goods  
13 with the intent not to sell the goods as advertised.  
14

15 52. Plaintiffs and the Class members are not sophisticated experts about the character,  
effectiveness, nature, level, or amount of antioxidants found in Bai5 Antioxidant Infusions or  
16 coffeefruit or white tea extracts. Plaintiffs and the Class acted reasonably when they purchased  
17 Bai5 Antioxidant Infusions based on their belief that Defendant's representations were true and  
18 lawful.  
19

20 53. Plaintiffs and the Class suffered injuries caused by Defendant because (a) they  
would not have purchased Bai5 Antioxidant Infusions on the same terms absent Defendant's illegal  
21 and misleading conduct as set forth herein, or if the true facts were known concerning Defendant's  
22 representations; (b) they paid a price premium for Bai5 Antioxidant Infusions due to Defendant's  
23 misrepresentations and unauthorized nutrient content claims; and (c) Bai5 Antioxidant Infusions  
24 did not have the characteristics, benefits, or quantities as promised.  
25

26 54. On or about October 4, 2014, prior to filing this action, a CLRA notice letter was  
served on Defendant which complies in all respects with California Civil Code § 1782(a). Plaintiff  
27 Lewin sent Bai Brands LLC, on behalf of herself and the proposed Class, a letter via certified mail,  
28

return receipt requested, advising Bai Brands that it is in violation of the CLRA and demanding that it cease and desist from such violations and make full restitution by refunding the monies received therefrom. A true and correct copy of Plaintiff Lewin's letter is attached hereto as Exhibit E.

55. Wherefore, Plaintiffs seek damages, restitution, and injunctive relief for these violations of the CLRA.

## COUNT II

## **Violation Of California's Unfair Competition Law, California Business & Professions Code §§ 17200, et seq.**

56. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint.

57. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class against Defendant.

58. Defendant is subject to California's Unfair Competition Law, Cal. Bus. & Prof. Code §§ 17200, *et seq.* The UCL provides, in pertinent part: "Unfair competition shall mean and include unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising ...."

59. Defendant's antioxidant nutrient content claims, including "Antioxidant Infusions," "Antioxidant Packed Beverage," "Antioxidant Packed," "We infuse the antioxidant power of the superfruit, add a splash of exotic fruit juices and voila! You have 100% natural, free-radical crushing, Bai 5," "Antioxidant Goodness Inside," "Hello Antioxidants!" and the "thermometer" graphic discussed above characterize the level of antioxidants in Bai5 Antioxidant Infusions and violate federal and California law because (1) there are no nutrients with RDIs in Bai5 Antioxidant Infusions, and (2) the antioxidant nutrient content claims do not include the nutrients that are subject of the claims or use a symbol to link the term "antioxidant" to those nutrients. Because Defendant's nutrient content claims do not comply with 21 C.F.R. § 101.54(g), Defendant sold misbranded products in California during the Class Period.

1       60.     Defendant's business practices, described herein, violated the "unlawful" prong of  
 2 the UCL by violating Section 403(r) of the FDCA [21 U.S.C. 343(r)(1)(a)], California Health &  
 3 Safety Code § 110670, the CLRA, the FAL and other applicable law as described herein.  
 4

5       61.     Defendant's business practices, described herein, violated the "unfair" prong of the  
 6 UCL in that their conduct is substantially injurious to consumers, offends public policy, and is  
 7 immoral, unethical, oppressive, and unscrupulous, as the gravity of the conduct outweighs any  
 8 alleged benefits. Defendant's advertising is of no benefit to consumers, and has been declared  
 9 misleading to consumers by the FDA, medical professionals, and research institutions.  
 10 Defendant's failure to comply with FDCA and parallel California labeling requirements and  
 11 deceptive advertising concerning the nature and effectiveness of antioxidants in Bai5 Antioxidant  
 12 Infusions offends the public policy advanced by the Act "to protect the public health" by ensuring  
 13 that "foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A).

14       62.     Defendant violated the "fraudulent" prong of the UCL by misleading Plaintiffs and  
 15 the Class to believe that the nutrient content claims made about Bai5 Antioxidant Infusions were  
 16 lawful, authorized claims that met the minimum nutritional requirements for such claims, as  
 17 described herein.

18       63.     Plaintiffs and the Class members are not sophisticated experts about the character,  
 19 effectiveness, nature, level, or amount of antioxidants found Bai5 Antioxidant Infusions or  
 20 coffeefruit or white tea extracts. Plaintiffs and the Class acted reasonably when they purchased  
 21 Bai5 Antioxidant Infusions based on their belief that Defendant's representations were true and  
 22 lawful.

23       64.     Plaintiffs and the Class lost money or property as a result of Defendant's UCL  
 24 violations because (a) they would not have purchased Bai5 Antioxidant Infusions on the same  
 25 terms absent Defendant's illegal conduct as set forth herein, or if the true facts were known  
 26 concerning Defendant's representations; (b) they paid a price premium for Bai5 Antioxidant  
 27 Infusions due to Defendant's misrepresentations and unauthorized nutrient content claims; and (c)  
 28 Bai5 Antioxidant Infusions did not have the characteristics, benefits, or quantities as promised.

### COUNT III

## **Violation Of California's False Advertising Law,**

## **California Business & Professions Code §§ 17500, et seq.**

65. Plaintiffs hereby incorporate by reference the allegations contained in all preceding paragraphs of this complaint

66. Plaintiffs bring this claim individually and on behalf of the members of the proposed Class against Defendant.

67. California's False Advertising Law, Cal. Bus. & Prof. Code §§ 17500, *et seq.*, makes it "unlawful for any person to make or disseminate or cause to be made or disseminated before the public in this state, ... in any advertising device ... or in any other manner or means whatever, including over the Internet, any statement, concerning ... personal property or services, professional or otherwise, or performance or disposition thereof, which is untrue or misleading and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

68. Defendant engaged in a scheme of offering misbranded bottles of Bai5 Antioxidant Infusions for sale to Plaintiffs and the Class members by way of product packaging, labeling, and other promotional materials. These materials misrepresented and/or omitted the true content and nature of the misbranded bottles of Bai5 Antioxidant Infusions. Defendant's advertisements and inducements were made in California and come within the definition of advertising as contained in Bus. & Prof. Code § 17500, *et seq.* in that the product packaging, labeling, and promotional materials were intended as inducements to purchase Defendant's Bai5 Antioxidant Infusions, and are statements disseminated by Defendant to Plaintiffs and the Class members. Defendant knew that these statements were unauthorized, inaccurate, and misleading.

69. Defendant's antioxidant nutrient content claims, including "Antioxidant Infusions," "Antioxidant Packed Beverage," "Antioxidant Packed," "We infuse the antioxidant power of the superfruit, add a splash of exotic fruit juices and voila! You have 100% natural, free-radical crushing, Bai 5." "Antioxidant Goodness Inside." "Hello Antioxidants!" and the "thermometer"

graphic discussed above characterize the level of antioxidants in Bai5 Antioxidant Infusions and violate federal and California law because (1) there are no nutrients with RDIs in Bai5 Antioxidant Infusions, and (2) the antioxidant nutrient content claims do not include the nutrients that are subject of the claims or use a symbol to link the term “antioxidant” to those nutrients. Because Defendant’s nutrient content claims do not comply with 21 C.F.R. § 101.54(g), Defendant sold misbranded products in California during the Class Period.

70. Defendant violated § 17500, *et seq.* by misleading Plaintiffs and the Class to believe that the nutrient content claims made about Bai5 Antioxidant Infusions were lawful, authorized claims that met the minimum nutritional requirements for such claims, as described herein.

71. Defendant knew or should have known, through the exercise of reasonable care that Bai5 Antioxidant Infusions was and continues to be misbranded, and that their representations about the antioxidant nutrient content of Bai5 Antioxidant Infusions were unauthorized, inaccurate, and misleading.

72. Plaintiffs and the Class lost money or property as a result of Defendant's FAL violations because (a) they would not have purchased Bai5 Antioxidant Infusions on the same terms absent Defendant's illegal conduct as set forth herein, or if the true facts were known concerning Defendant's representations; (b) they paid a price premium for Bai5 Antioxidant Infusions due to Defendant's misrepresentations and unauthorized nutrient content claims; and (c) Bai5 Antioxidant Infusions did not have the characteristics, benefits, or quantities as promised.

## **PRAYER FOR RELIEF**

**WHEREFORE**, Plaintiffs, individually and on behalf of all others similarly situated, seek judgment against Defendant, as follows:

- a. For an order certifying the Class under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiffs as representatives of the Class and Plaintiffs' attorneys as Class Counsel to represent the Class members;
  - b. For an order declaring that Defendant's conduct violates the statutes referenced herein:

- c. For an order finding in favor of Plaintiffs and the Class on all counts asserted herein;
  - d. For compensatory and punitive damages in amounts to be determined by the Court and/or jury;
  - e. For prejudgment interest on all amounts awarded;
  - f. For an order of restitution and all other forms of equitable monetary relief;
  - g. For injunctive relief as pleaded or as the Court may deem proper; and
  - h. For an order awarding Plaintiffs and the Class their reasonable attorneys' fees and expenses and costs of suit.

## **DEMAND FOR TRIAL BY JURY**

Plaintiffs demand a trial by jury of all issues so triable.

Dated: November 19, 2014

Respectfully submitted,

## **BURSOR & FISHER, P.A.**

By: /s/ Annick Persinger  
Annick M. Persinger

L. Timothy Fisher (State Bar No. 191626)  
Annick M. Persinger (State Bar No. 272996)  
Yeremey Krivoshey (State Bar No. 295032)  
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apersinger@bursor.com  
ykrivoshey@bursor.com

*Attorneys for Plaintiff*

1                   **CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)**  
2

3                   I, Samantha Lewin, declare as follows:

4                   1.       I am a plaintiff in this action and a citizen of the State of California. I have personal  
5 knowledge of the facts stated herein and, if called as a witness, I could and would testify  
6 competently thereto.

7                   2.       The complaint filed in this action is filed in the proper place because Bai Brands  
8 LLC sells hundreds of thousands of bottles of its products, including Bai5 Antioxidant Infusions, in  
9 this District.

10                  3.       While living in San Francisco, California, I purchased numerous bottles of Bai5  
11 Antioxidant Infusions within this District, including Bai5 Antioxidant Infusions: Molokai Coconut  
12 and Bai5 Antioxidant Infusions: Ipanema Pomegranate, for my personal use. I purchased Bai5  
13 Antioxidant Infusions after I read statements on the bottles' labels characterizing the antioxidants  
14 inside, such as "Antioxidant Packed Beverage," "Antioxidant Goodness Inside" and "Antioxidant  
15 Packed." The representations on the label were substantial factors influencing my decision to  
16 purchase Bai5 Antioxidant Infusions. I would not have purchased Bai5 Antioxidant Infusions had  
17 I known that the bottles were misbranded and mischaracterized the amounts and nature of the  
18 nutrients and antioxidants inside.

19  
20                  I declare under the penalty of perjury under the laws of the State of California that the  
21 foregoing is true and correct, executed on November 11, 2014 at San Francisco, California.

22  
23  
24                    
25  
26  
27  
28

SAMANTHA LEWIN

1                   **CLRA Venue Declaration Pursuant to California Civil Code Section 1780(d)**

2                   I, Dorinda Vassigh, declare as follows:

3                   1.         I am a plaintiff in this action and a citizen of the State of California. I have personal  
4 knowledge of the facts stated herein and, if called as a witness, I could and would testify  
5 competently thereto.

6                   2.         The complaint filed in this action is filed in the proper place because Bai Brands  
7 LLC sells hundreds of thousands of bottles of its products, including Bai5 Antioxidant Infusions, in  
8 this District.

9                   3.         While living in San Francisco, California, I purchased numerous bottles of Bai5  
10 Antioxidant Infusions within this District, including Bai5 Antioxidant Infusions: Molokai Coconut,  
11 for my personal use. I purchased Bai5 Antioxidant Infusions after I read statements on the bottles'  
12 labels characterizing the antioxidants inside, such as "Antioxidant Packed Beverage," "Antioxidant  
13 Goodness Inside" and "Antioxidant Packed." The representations on the label were substantial  
14 factors influencing my decision to purchase Bai5 Antioxidant Infusions. I would not have  
15 purchased Bai5 Antioxidant Infusions had I known that the bottles were misbranded and  
16 mischaracterized the amounts and nature of the nutrients and antioxidants inside.

17                   I declare under the penalty of perjury under the laws of the State of California that the  
18 foregoing is true and correct, executed on November 19, 2014 at San Francisco, California.

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28



DORINDA VASSIGH

**EXHIBIT A**



# U.S. Food and Drug Administration

Protecting and Promoting Your Health

[Home Inspections, Compliance, Enforcement, and Criminal Investigations](#) [Compliance Actions and Activities](#) [Warning Letters](#)  
**Inspections, Compliance, Enforcement, and Criminal Investigations**

Unilever United States, Inc. 8/23/10



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
College Park, MD 20740

August 23, 2010

## WARNING LETTER

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

Mr. Michael B. Polk  
President of Unilever Americas  
Unilever, Inc.  
700 Sylvan Avenue  
Englewood, NJ 07632-3113

Re: CFSAN-OC-10-24

Dear Mr. Polk:

The Food and Drug Administration (FDA) has reviewed the label for your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product and reviewed your labeling for this product on your websites, [www.lipton.com](http://www.lipton.com)<sup>1</sup> and [www.liptont.com](http://www.liptont.com)<sup>2</sup> in August 2010. Based on our review, we have concluded that this product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at [www.fda.gov](http://www.fda.gov)<sup>3</sup>.

A link to .your website, [www.lipton.com](http://www.lipton.com)<sup>4</sup>. appears on your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product label. This website directs U.S. visitors to another website, [www.liptont.com](http://www.liptont.com)<sup>5</sup>. We have determined that your websites, [www.lipton.com](http://www.lipton.com)<sup>6</sup> and [www.liptont.com](http://www.liptont.com)<sup>7</sup>. are labeling within the meaning of section 201(m) of the Act for your "Lipton Green Tea 100% Natural Naturally Decaffeinated" product.

### Unapproved New Drug

Your website, [www.liptont.com](http://www.liptont.com)<sup>8</sup>. also promotes your Lipton Green Tea 100% Natural Naturally Decaffeinated product for conditions that cause it to be a drug under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)].

For example, your webpage entitled "Tea and Health," subtitled "Heart Health Research" and further subtitled "Cholesterol Research" bears the following claim: "[F]our recent studies in people at risk for coronary disease have shown a significant cholesterol lowering effect from tea or tea flavonoids ... One of these studies, on post-menopausal women, found that total cholesterol was lowered by 8% after drinking 8 cups of green tea daily for 12 weeks ...."

The therapeutic claims on your website establish that the product is a drug because it is intended for use in the cure, mitigation, treatment, or prevention of disease. Your Lipton Green Tea 100% Natural Naturally Decaffeinated product is not generally recognized as safe and effective for the above referenced uses and,

therefore, the product is a "new drug" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C.

§ 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your Lipton Green Tea 100% Natural Naturally Decaffeinated product is offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use this drug safely for its intended purposes. Thus, your Lipton Green Tea 100% Natural Naturally Decaffeinated product is misbranded under section 502(f)(1) of the Act in that the labeling for this drug fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)] .

### **Unauthorized Nutrient Content Claims**

Under section 403(r)(1)(A) of the Act [21 U.S.C. 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

Your webpage entitled "Tea and Health" and subtitled "Tea Antioxidants" includes the statement, "LIPTON Tea is made from tea leaves rich in naturally protective antioxidants." The term "rich in" is defined in 21 CFR 101.54(b) and may be used to characterize the level of antioxidant nutrients (21 CFR 101.54(g)(3)). However, this claim does not comply with 21 CFR 101.54(g)(4) because it does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients. Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.

This webpage also states that "tea is a naturally rich source of antioxidants." The term "rich source" characterizes the level of antioxidant nutrients in the product and, therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "rich source" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "tea is a naturally rich source of antioxidants" does not include the nutrients that are the subject of the claim or use a symbol to link the term "antioxidant" to those nutrients, as required by 21 CFR 101.54(g)(4). Thus, this claim misbrands your product under section 403(r)(2)(A)(i) of the Act.

The product label back panel includes the statement "packed with protective FLAVONOID ANTIOXIDANTS." The term "packed with" characterizes the level of flavonoid antioxidants in the product; therefore, this claim is a nutrient content claim (see section 403(r)(1) of the Act and 21 CFR 101.13(b)). Even if we determined that the term "packed with" could be considered a synonym for a term defined by regulation, nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). The claim "packed with FLAVONOID ANTIOXIDANTS" does not comply with 21 CFR 101.54(g)(1) because no RDI has been established for flavonoids. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or

injunction.

We note that your label contains a chart entitled "Flavonoid Content of selected beverages and foods." The chart appears to compare the amounts of antioxidants in your product with the amount of antioxidants in orange juice, broccoli, cranberry juice and coffee. However, the information provided may be misinterpreted by the consumer because although the chart is labeled, in part, "Flavonoid Content," the y-axis is labeled "AOX"; therefore, the consumer might believe that the chart is stating the total amount of antioxidants rather than specifically measuring the amount of flavonoids in the product.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Latasha A. Robinson, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/s/

Jennifer A. Thomas  
Acting Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition

cc: FDA New Jersey District

### **Close Out Letter**

- [Unilever United States, Inc. - Close Out Letter 5/10/11<sup>9</sup>](#)

Page Last Updated: 08/09/2011

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

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Silver Spring, MD 20993  
Ph. 1-888-INFO-FDA (1-888-463-6332)  
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[Inspections/Compliance](#) [State & Local Officials](#) [Consumers](#) [Industry](#) [Health Professionals](#) [FDA Archive](#)



### **Links on this page:**

1. <http://www.lipton.com/>

2. <http://www.liptont.com/>
3. <http://www.fda.gov>
4. <http://www.lipton.com/>
5. <http://www.liptont.com/>
6. <http://www.lipton.com/>
7. <http://www.liptont.com/>
8. <http://www.liptont.com/>
9. /ICECI/EnforcementActions/WarningLetters/2010/ucm267398.htm

**EXHIBIT B**



# U.S. Food and Drug Administration

Protecting and Promoting Your Health

[Home Inspections, Compliance, Enforcement, and Criminal Investigations](#) [Compliance Actions and Activities](#) [Warning Letters](#)  
**Inspections, Compliance, Enforcement, and Criminal Investigations**

**Redco Foods, Inc. 2/22/10**



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
College Park, MD 20740

**FEB 22 2010**

## **WARNING LETTER**

### **VIA OVERNIGHT MAIL**

Mr. Douglas N. Farrell, General Manager  
Redco Foods, Inc.  
One Hansen Island  
Little Falls, NY 13365

Re: CFSAN-OC-10-10

Dear Mr. Farrell:

The Food and Drug Administration (FDA) has reviewed the label for your "Salada Naturally Decaffeinated Green Tea" product and your website [www.greentea.com](http://www.greentea.com). Based on our review, we have concluded that your green tea products are in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at [www.fda.gov](http://www.fda.gov).

### **Unapproved New Drug**

Your website, [www.greentea.com](http://www.greentea.com), promotes your green tea products for conditions that cause them to be drugs under section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. Examples of disease claims that cause your products to be drugs include:

**On a web page entitled "About Green Tea":**

**"A Steaming Cup of Medicine" Article:**

- "And today, scientific [sic] are ... finding that green tea can ... inhibit the cancer process at virtually every stage, regulate cholesterol levels ... and ward off viruses, fungi and food-borne bacteria."
- "[I]t also helps inhibit dental plaque formation, lower the risk of type 2 diabetes ...."

**"The Origins of Tea" Article:**

- "By this time, tea was prized as a medicine that could cure digestive disorders ..."
- "The tea leaves were also applied externally as a paste to ease the pains of rheumatism."

#### **"Is Green Tea a Brain Food?" Article:**

- "[R]ecent studies of the effects of green tea's catechins on animal brains are intriguing:
  - o "\* Less buildup of plaque[.] Finally, mice specially bred to develop Alzheimer's disease developed up to 54% less beta-amyloid buildup in their brains when they were given daily injections of the green tea catechin EGCg.... Beta-amyloid plaques are believed to be a major cause of the brain cell death and tissue [tissue] loss seen in Alzheimer's disease."

The therapeutic claims on your website establish that your green tea products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Your green tea products are not generally recognized as safe and effective for the above referenced uses and, therefore, the products are "new drugs" under section 201 (p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

Your green tea products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layperson can use these drugs safely for their intended purposes. Thus, your green tea products are misbranded under section 502(f)(1) of the Act in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)].

#### **Unauthorized Health Claims**

Your green tea products are further misbranded under section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because its labeling bears unauthorized health claims. Your website, [www.greentea.com](http://www.greentea.com). was reviewed and was found to contain a number of unauthorized health claims, including:

#### **"Green Tea and the FDA: Who's Right?" Article:**

- "[O]ver the past 25 years, countless studies showing the positive effect of green tea on several important risk factors for cardiovascular disease have been published in scientific journals."
- "[M]ost studies have shown that green tea reduces certain CVD risk factors with a daily intake of 4-5 cups ...."

The above claims are unauthorized health claims because there is no health claim authorized by regulation or the Act that provides for health claims that characterize the relationship between green tea and cardiovascular disease.

#### **Unauthorized Nutrient Content Claims**

Under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)], a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, an RDI must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant vitamin C," the product must contain 20 percent or more of the RDI for vitamin C under 21 CFR 101.54(b)). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

The principal display panel of the product label includes the statement "Fortified with Purple Antioxidants [/ Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins ...". In the context of the label, the term "antioxidants" refers, in part, to grapeskins, rooibos (red tea), and anthocyanins. The term "fortified" is defined by regulation and may be used to describe the level of certain substances for which an RDI or Daily Reference Value (DRV) has been established [21 CFR 101.54(e)]. However, there are no RDIs or DRVs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Grapeskins, Rooibos (Red Tea), Anthocyanins" is unauthorized and misbrands your product under section 403(r)(1)(A) of the Act.

In addition, nutrient content claims using the term "antioxidant" may only be made for nutrients for which a Reference Daily Intake (RDI) has been established [21 CFR 101.54(g)(1)]. As noted above, there are no RDIs for grapeskins, rooibos (red tea) or anthocyanins. Therefore, the claim "Fortified with Purple Antioxidants ... Grapeskins. Rooibos (Red Tea), Anthocyanins" is an unauthorized nutrient content claim that causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The label for this product also bears the unauthorized nutrient content claim "One of the antioxidants known as EGCG (Epigallocatechin gallate) is abundantly found in green tea leaves." This claim is a nutrient content claim because "abundantly found" characterizes the level of EGCG in your product [see section 403(r)(1) of the Act (21 U.S.C. § 343(r)(1)) and 21 CFR 101.13(b)]. Even if we determined that the term "abundantly found" could be considered a synonym for a term defined by regulation (e.g., "high" or "good source"), nutrient content claims that use the term "antioxidant" must meet the requirements of 21 CFR 101.54(g). This claim does not comply with 21 CFR 101.54(g)(1) because no RDI has been established for EGCG. Thus, this unauthorized nutrient content claim causes your product to be misbranded under section 403(r)(2)(A)(i) of the Act.

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

You should take prompt action to correct these violations. Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Kathleen M. Lewis, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/S/

Roberta F. Wagner  
Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition

cc: FDA New York District

Page Last Updated: 03/03/2010

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### Links on this page:

**EXHIBIT C**



## Inspections, Compliance, Enforcement, and Criminal Investigations



Home  Inspections, Compliance, Enforcement, and Criminal Investigations  Compliance Actions and Activities  Warning Letters

### Dr Pepper Snapple Group 8/30/10



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
College Park, MD 20740

AUG 30 2010

#### WARNING LETTER

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

Mr. Larry D. Young  
President and CEO  
Dr Pepper Snapple Group  
5301 Legacy Drive  
Plano, Texas 75024

Re: CFSAN-OC-10-26

Dear Mr. Young:

The Food and Drug Administration (FDA) has reviewed the label for your Canada Dry Sparkling Green Tea Ginger Ale. We examined the product label and your website at [www.canadadry.com](http://www.canadadry.com) in July of 2010. Based on our review, we have concluded that your green tea ginger ale product is in violation of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Act and regulations on FDA's website at [www.fda.gov](http://www.fda.gov).

Your Sparkling Green Tea Ginger Ale is misbranded within the meaning of section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product label bears a nutrient content claim that is not authorized by regulation. Under section 403(r)(2)(A)(i) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. The use of a term, not defined by regulation, in food labeling to characterize the level of a nutrient misbrands a product under section 403(r)(1)(A) of the Act.

Your Sparkling Green Tea Ginger Ale bears the claim, "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\*" with the double asterisk referring to the statement, "Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" on the principal display panel of the product label. In the context of this label the term "enhanced" is an unauthorized synonym for a "more" nutrient content claim. FDA has defined the nutrient content claim "more" and its authorized synonyms in 21 CFR 101.54(e).

"More" nutrient content claims may be used on the label or in the labeling of foods to describe the level of nutrients, provided that (1) the food contains at least 10 percent more of the Reference Daily Intake or Daily Reference Value for the nutrient per reference amount customarily consumed than an appropriate reference food, (2) where the claim is based on nutrients that are added to the food, that the fortification is in accordance with the policy on fortification of foods in 21 CFR 104.20, and (3) the claim bears the required information for relative claims as described in 21 CFR 101.130(2) and 101.54(e)(1)(iii).

Your Sparkling Green Tea Ginger Ale is a carbonated beverage. The policy on fortification in 21 CFR 104.20(a) states that the FDA does not consider it appropriate to fortify snack foods such as carbonated beverages. Additionally, the label of your product does not state the identity of a reference food and the percentage (or fraction) of the amount of the nutrient(s) in the reference food by which the nutrient(s) in the labeled food differs, as is required for "more" nutrient content claims under 101.130(2). Therefore, even if the term "enhanced" was an authorized synonym for "more," your product would not meet the requirements for a "more" claim under 21 CFR 101.54(e)(1).

Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a Reference Daily Intake (RDI) must have been established for each of the nutrients that are the subject of the claim (21 CFR 101.54(g)(1)), and these nutrients must have recognized antioxidant activity (21 CFR 101.54(g)(2)). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e) (21 CFR 101.54(g)(3)). For example, to bear the claim "high in antioxidant Vitamin C," the product must contain 20 percent or more of the RDI for Vitamin C under 21 CFR 101.54(b). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that

**Case 4:14-cv-05127-HSG Document 1 Filed 11/19/14 Page 38 of 45**

appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity (21 CFR 101.54(g)(4)). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

The nutrient content claim for your Sparkling Green Tea Ginger Ale product of "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\* .... \*\*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" identifies Vitamin C as a nutrient associated with the antioxidant claim. Vitamin C is a nutrient that is a recognized source of antioxidants. Your Nutrition Facts panel declares Vitamin C at 100% of the Daily Reference Value (DRV), which accounts for 60 mg of the claimed 200 mg of antioxidants. According to the nutrient content claim on your product label, the remainder 140 mg of antioxidants must be derived from green tea or green tea flavonoids, which are not nutrients with recognized antioxidant activity under 21 CFR § 101.54(g)(2). Therefore, the claim "ENHANCED WITH 200 mg OF ANTIOXIDANTS FROM GREEN TEA & VITAMIN C\*\* .... \*\*Each 8 oz serving contains 200 mg of antioxidants from Green Tea Flavonoids and Vitamin C" does not meet the requirements of 21 CFR 101.54(g) and misbrands your product under section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products or their labeling. It is your responsibility to ensure that all of your products are in compliance with the laws and regulations enforced by FDA. You should take prompt action to correct these violations. Failure to promptly correct these violations may result in regulatory actions without further notice, such as seizure and/or injunction.

Please respond to this letter within 15 days from receipt with the actions you plan to take in response to this letter, including an explanation of each step being taken to correct the current violations and prevent similar violations. Include any documentation necessary to show that correction has been achieved. If you cannot complete corrective action within fifteen working days, state the reason for the delay and the time within which you will complete the correction.

You should direct your written reply to Judith G. Dausch, Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Parkway, Office of Compliance (HFS-608), Division of Enforcement, College Park, Maryland 20740-3835.

Sincerely,

/s/

Jennifer Thomas  
Acting Director  
Office of Compliance  
Center for Food Safety  
and Applied Nutrition

cc: FDA Dallas District

Page Last Updated: 09/14/2010

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U.S. Department of Health & Human Services

**EXHIBIT D**



## Inspections, Compliance, Enforcement, and Criminal Investigations



Home  Inspections, Compliance, Enforcement, and Criminal Investigations  Compliance Actions and Activities  Warning Letters

### Diaspora Tea & Herb dba Rishi Tea 4/20/11



Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Minneapolis District Office  
Central Region  
250 Marquette Avenue, Suite 600  
Minneapolis, MN 55401  
Telephone: (612) 334-4100  
FAX: (612) 334-4142

April 20, 2011

#### WARNING LETTER

#### CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 11 – 21

Joshua Kaiser  
President and Co-owner  
Diaspora Tea & Herb Co., LLC  
427 East Stewart Street  
Milwaukee, Wisconsin 53207

Dear Mr. Kaiser:

This is to advise you that the Food and Drug Administration (FDA) reviewed your website at the Internet address <http://www.rishi-tea.com/store/index.php> in January 2011. FDA has determined that your Oolong Tea, Ginger, Organic Botanical, Green Oolong Tea, 100% Premium Tealeaf Powder, and Pu-erh Tea products are promoted for conditions that cause the products to be drugs under section 201(g)(1)(B) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 321(g)(1)(B). The therapeutic claims on your website establish that these products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. Additionally, FDA has determined that your Yerba Maté Shade Grown, Organic Yerba Maté, White Tea, Pu-erh Tea, Green Oolong Tea, 100% Premium Tealeaf Powder, Matcha, 100% Premium Tea Powder, Blueberry Rooibos, Organic Fair Trade Rooibos Blend, Green Rooibos (Green Bush), Organic Fair Trade Botanical, and Super Green, Organic Japanese Green Tea products are also misbranded within the meaning of section 403(r)(1)(A) of the Act, 21 U.S.C. § 343(r)(1)(A). The marketing of these products with these claims violates the Act. You can find copies of the Act through links on FDA's home page at <http://www.fda.gov>.

#### I. Unapproved New Drugs

Examples of disease claims on your website <http://www.rishi-tea.com/store/index.php> include:

##### Ginger, Organic Botanical

- "[G]inger is used in food and drinks as a preventive medicine against colds [and] flus."

##### Green Oolong Tea, 100% Premium Tealeaf Powder

- "The powerful antioxidants found in tea are believed to help prevent cancer [and] lower cholesterol...."

##### Pu-erh Tea

- "Recent research suggests that consuming 5-8 cups of Pu-erh Tea each day can reduce cholesterol and plaque of the arteries."

##### Oolong Tea

- "Regular consumption of Oolong Tea is linked to the reduction of plaque in the arteries, reduction of cholesterol and lowering of blood sugar."
- "Oolong Tea is...prized for its cholesterol reducing...."

Your Oolong Tea, Ginger, Organic Botanical, Green Oolong Tea, 100% Premium Tealeaf Powder and Pu-erh

**Case 4:14-cv-05127-HSG Document 1 Filed 11/19/14 Page 41 of 45**

Tea products are not generally recognized as safe and effective for the above referenced uses and, therefore, are also "new drugs" under section 201(p) of the Act, 21 U.S.C. § 321(p). New drugs may not be legally marketed in the U.S. without prior approval from FDA, as described in section 505(a) of the Act, 21 U.S.C. § 355(a). FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

**II. Unauthorized Nutrient Content Claims**

Under section 403(r)(1)(A) of the Act, a claim that characterizes the level of a nutrient which is of the type required to be in the labeling of the food must be made in accordance with a regulation promulgated by the Secretary (and, by delegation, FDA) authorizing the use of such a claim. Characterizing the level of a nutrient in food labeling of a product without complying with specific requirements pertaining to nutrient content claims for that nutrient misbrands the product under section 403(r)(1)(A) of the Act.

Nutrient content claims that use the defined terms "rich in" or "high" may be used in the labeling of a food only if the food contains 20 percent or more of the daily value (DV) of that nutrient per reference amount customarily consumed (RACC), Title 21, Code of Federal Regulations (21 CFR), 101.54(b)(1). Such claims may not be made about a nutrient for which there is no established DV. However, your website bears "high" and "rich in" nutrient content claims about nutrients for which there are no established DV.

The following are examples of unauthorized "high" and "rich in" nutrient content claims on your website:

**Pu-erh Tea**

- "[R]ich in Tea Polyphenols and Theaflavins...rich in Thearubigin and Theabrownin...."

**Super Green, Organic Japanese Green Tea**

- "Super Green is...high in amino acids...."

**White Tea**

- "White Tea...contain[s] high concentrations of...L-Theanine Amino Acid."

Additionally, your website bears nutrient content claims using the term "antioxidant." Nutrient content claims using the term "antioxidant" must also comply with the requirements listed in 21 CFR 101.54(g). These requirements state, in part, that for a product to bear such a claim, a Recommended Daily Intake (RDI) must have been established for each of the nutrients that are the subject of the claim, 21 CFR 101.54(g)(1), and these nutrients must have recognized antioxidant activity, 21 CFR 101.54(g)(2). The level of each nutrient that is the subject of the claim must also be sufficient to qualify for the claim under 21 CFR 101.54(b), (c), or (e), 21 CFR 101.54(g)(3). Such a claim must also include the names of the nutrients that are the subject of the claim as part of the claim or, alternatively, the term "antioxidant" or "antioxidants" may be linked by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity, 21 CFR 101.54(g)(4). The use of a nutrient content claim that uses the term "antioxidant" but does not comply with the requirements of 21 CFR 101.54(g) misbrands a product under section 403(r)(2)(A)(i) of the Act.

The following are examples of nutrient content claims on your website that use the term "antioxidant" but do not include the names of the nutrients that are the subject of the claim as required under 21 CFR 101.54(g)(4):

**Yerba Maté Shade Grown, Organic Yerba Maté**

- "Yerba Maté is...rich in... antioxidants."

**Blueberry Rooibos, Organic Fair Trade Rooibos Blend**

- "Antioxidant-rich...."

**Green Rooibos (Green Bush), Organic Fair Trade Botanical**

- "Caffeine-free Green Rooibos...contain[s] high concentrations of antioxidants...."

Additionally, the following are examples of nutrient content claims on your website that use the term "antioxidant," but where the nutrients that are the subject of the claim do not have an established RDI as required under 21 CFR 101.54(g)(1):

**White Tea**

- "White Tea... contain[s] high concentrations of... antioxidant polyphenols (tea catechins)...."

**Matcha, 100% Premium Tea Powder**

- "Antioxidant rich...222mg polyphenols per serving!"

**Genmai Green Tea, 100% Premium Tealeaf Powder**

- "Antioxidant rich...65mg polyphenols per serving!"

**Green Oolong Tea, 100% Premium Tealeaf Powder**

- "Antioxidant rich...109mg polyphenols per serving!"
- "[R]ichest sources of flavonoid antioxidants...."

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We urge you to review your website, product labels, and other labeling and promotional materials for your products to ensure that the claims you make for your products do not cause them to violate the Act. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products, 21 U.S.C. §§ 332 and 334. You should take prompt action to correct these violations and prevent their future recurrence. Failure to do so may result in enforcement action without further notice.

Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific actions you are taking to correct these violations and to prevent similar violations. You should include in your response documentation such as revised labels or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for the delay and state when you will correct any remaining violations.

Your reply should be sent to the attention of Compliance Officer Tyra S. Wisecup at the address on the

letterhead.

Sincerely,

/s/

Gerald J. Berg  
Director  
Minneapolis District

## Close Out Letter

- Diaspora Tea & Herb Co., LLC - Close Out Letter 2/3/12

Page Last Updated: 02/10/2012

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U.S. Department of **Health & Human Services**

**EXHIBIT E**



1990 N. California Blvd.  
SUITE 940  
WALNUT CREEK, CA 94596  
[www.bursor.com](http://www.bursor.com)

ANNICK M. PERSINGER  
YEREMEY KRIVOSHEY  
Tel: 925.300.4455  
Fax: 925.407.2700  
[apersinger@bursor.com](mailto:apersinger@bursor.com)  
[ykrivoshey@bursor.com](mailto:ykrivoshey@bursor.com)

September 30, 2014

**Via Certified Mail - Return Receipt Requested**

Bai Brands LLC  
1800 E. State Street Ste. 153  
Hamilton, New Jersey 08609

*Re: Demand Letter Pursuant to California Civil Code § 1782,  
Violation of Magnuson-Moss Act, 15 U.S.C. §§ 2301, et seq., and other applicable laws.*

To Whom It May Concern:

This letter serves as a notice and demand for corrective action on behalf of my client, Samantha Lewin, and all other persons similarly situated, arising from breaches of warranty under the Magnuson-Moss Warranty Act and violations of numerous provisions of California law including the Consumers Legal Remedies Act, Civil Code § 1770, including but not limited to subsections (a)(5), (7), and (9). This letter also serves as notice pursuant to Cal. Com. Code § 2607(3)(a) concerning the breaches of express and implied warranties described herein.

You have participated in the manufacture, marketing, and sale of Bai5 Antioxidant Infusions. Bai5 Antioxidant Infusions labels include unauthorized nutrient content claims in violation of 21 C.F.R. 101.54(g), as well as federal and state law. As a result, Bai5 Antioxidant Infusions products are misbranded.

Ms. Lewin, a resident of California, purchased Bai5 Antioxidant Infusions based on the antioxidant representations on the label. She would not have purchased Bai5 Antioxidant Infusions absent the antioxidant claims on the label.

Ms. Lewin is acting on behalf of a class defined as all persons in California who purchased Bai5 Antioxidant Infusions (hereafter, the "Class").

To cure the defects described above, we demand that you (1) cease and desist from continuing to mislabel Bai5 Antioxidant Infusions; (2) issue an immediate recall on any Bai5 Antioxidant Infusion products bearing misbranded labels; and (3) make full restitution to all California purchasers of Bai5 Antioxidant Infusions of all purchase money obtained from sales thereof.

We further demand that you preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the ingredients, formula, and manufacturing process for Bai5 Antioxidant Infusions;
2. All communications with the U.S. Food and Drug Administration concerning the product development, manufacturing, marketing and sales of Bai5 Antioxidant Infusions;
3. All documents concerning the advertisement, marketing, or sale of Bai5 Antioxidant Infusions; and
4. All communications with customers concerning complaints or comments concerning Bai5 Antioxidant Infusions.

We are willing to negotiate to attempt to resolve the demands asserted in this letter. If you wish to enter into such discussions, please contact me immediately. If I do not hear from you promptly, I will conclude that you are not interested in resolving this dispute short of litigation. If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents promptly.

Very truly yours,



Annick M. Persinger